specification. This paper copy was generated from the computer readable form submitted herewith, and is identical to that originally filed in the international application.

Beginning on page 2 of the Office Action, the Examiner has set forth a restriction requirement which separates the claims into three groups:

Group I, claims 1-9 and 21, "drawn to a pharmaceutical composition comprising of early and late proteins of papillomavirus;"

Group II, claims 10-20 and 25-31 "drawn to expression vector for a fusion protein comprising early and late genes;" and

Group III, claims 23 and 24, "drawn to a method of treatment for cancer."

The Examiner's reasons for the restriction are that the three groups allegedly fail to relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical feature. In the Examiner's opinion, the special technical feature is lacking because "the teaching of Zhou et al... overlap[s] with the invention of Group I" and that "[Zhou] disclosed the fusion protein of early and late proteins of papillomavirus." Applicants respectfully traverse the restriction requirement and request that the Examiner reconsider.

First, applicants note that the reasons given for the restriction do not appear to make any sense, and it is not at all clear on what basis the Examiner is forms his reasoning. In fact, it appears that the Examiner is actually setting forth a prior art rejection based on Zhou, to which applicants strenuously object in view of the fact that this Action sets forth neither the appropriate laws nor the required showing for a prior art rejection.

Moreover, while applicants understand that the Examiner is burdened with meeting a certain quantity of examination, applicants are dismayed at the level of attention reflected in the Action. When the Examiner neglects to back up the restriction requirement with a reasoned analysis, it makes it extremely difficult for the applicants to respond appropriately, because in order to do so they must read the Examiner's mind. This is unfair to the Applicants, who are relying on a thorough examination process to ensure a valid patent.

The Examiner relies on PCT Rule 13 to support the restriction. PCT Rule 13 says that a group of inventions is considered to form a single inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding technical feature. A common technical feature is defined as meaning one which defines the contribution that each claimed invention makes over the prior art.

The specific combination of early and late proteins referred to in claim 1, AND claim 10 AND claims 23 and 24 (because they depend on claim 1) satisfies the requirement of the special technical feature. Indeed, claim 1 is directed to a pharmaceutical composition which comprises at least one polypeptide from the early region of a human papillomavirus and at least one polypeptide from the late region of a human papillomavirus, and/or at least one polypeptide having immunostimulatory activity. Claim 10 is also directed to a pharmaceutical composition (not a vector as specified in the Office Action), wherein the composition comprises, as therapeutic agents, one or more vectors which code for at least one polypeptide from the early region of a human papillomavirus and at least one

polypeptide from the late region of a human papillomavirus, and/or at least one polypeptide having immunostimulatory activity. And claims 23 and 24 are directed to methods of treatment comprising administering the pharmaceutical composition of claim 1.

Thus, the common technical feature of all the claims is the combination of early and late proteins and optionally or alternatively the immunostimulatory protein. Such is provided directly by the proteins in the pharmaceutical composition of claim 1; it is provided by the vectors referenced in claim 10 since these encode the same proteins. And it is certainly provided in the treatment method recited in claims 23 and 24, since these claims are dependent on claim 1.

The Examiner is respectfully requested to review Annex B of the PCT Administrative Instructions, provided in the MPEP. In particular, according to these instructions, unity of invention exists between claims directed to (1) a method of manufacturing X, (2) substance X, and (3) the use of substance X (as an insecticide, for example). The special technical feature among this group of claims is "X".

When the claims of the instant application are compared to the exemplary situation discussed above, it is clear that unity of invention would also exist between all the claims of the instant application. Indeed, if a particular combination of viral proteins is seen as equivalent to "X" above, then Group I as defined in the restriction requirement would have this technical feature because it contains "X". Group II would have this technical feature because it is directed to a composition comprising DNA encoding "X". And Group III

would have this technical feature because it is directed to methods of using "X" to treat cancer.

Thus, the claims of the instant application clearly have unity of invention and share a special technical feature, and it is not clear how Zhou or any other reference would affect this basic premise. Again, unity of invention is a different question than novelty or obviousness, and reference to Zhou or any other reference fails to address the relevant question, that is, what is the relationship between the instant claims.

Applicants respectfully request that the Examiner reconsider the restriction requirement after reviewing the rules regarding unity of invention, or, at the very least, explain why the instant claims do not have unity of invention in light of the above discussion. While applicants are aware that the Examiner is given wide discretion as to when to restrict the claims, this discretion does not warrant a total disregard of the PCT Rules, which are designed to ensure that international applications receive a proper and thorough examination in the national stage.

Solely in order to comply with 37 CFR §1.143, applicants elect Group I with traverse.

Should the Examiner have any questions concerning the subject application, a telephone call to the undersigned would be appreciated.

Respectfully submitted,

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